

K061553

JUL 17 2006

Appendix J
510(k) Summary Sheet

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and FDA 1000ML Watertight test Standards..... Appendix J, Page 2



YTY INDUSTRY (MANJUNG) SDN. BHD.

(Company No : 380830-P)

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APPENDIX-J

1.0 SMDA 510 (K) SUMMARY

2.0 Submitter YTY Industry (Manjung) Sdn Bhd
Lot 1422-1424, Batu 10 Lekir
32020 Sitiawan
Perak Darul Ridzuan
MALAYSIA

Tel 605-6792288

Fax 605-6791188

Name of Contact Person 1. MR. MOH UNG NANG

Official Correspondence 2. MS. JANNA TUCKER

Date of Summary Prepared May 2, 2006

3.0 Name of Device

Trade Name: Non-Sterile, Powder-Free, Black Nitrile Examination Gloves.

Common Name: Synthetic Rubber Examination Gloves

Classification Name: Patient Examination Glove, Powder Free

4.0 Identification of The Legally Marketed Devices

Black Colour Powder Free Nitrile Examination Gloves as described in this 510k Notification is substantially equivalent to the current Class I patient examination glove bearing the product code 80LZA (21CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D6319-00a ¹ Standard Specification for Nitrile Gloves for Medical Application.

EQUIVALENT TO R052502 EXCEPT FOR COLOR.

5.0 Description of The Device

Black Colour Powder Free Nitrile Examination Gloves meets all the current specifications listed under the ASTM Specification D6319-00a ¹ Standard Specification for Nitrile Examination Gloves for Medical Application.

6.0 The Intended Use of Glove

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

7.0 Summary of Performance Data:

Performance data of gloves based on ASTM D6319-00a^{E3} and FDA 1000ML watertight test.

TEST	ASTM D6319-00a ^{E3}	POWDER FREE NITRILE EXAMINATION GLOVES
1. Watertight (1000ml)	Multiple Normal GII AQL = 2.5	Pass GII AQL = 2.5
2. Length (mm) Size XS S M L XL	Min 220 Min 220 Min 230 Min 230 -	240 mm minimum for all sizes
3. Palm width (mm) Size XS S M L XL	70 ± 10 80 ± 10 95 ± 10 111 ± 10 -	73 – 78 83 – 88 93 – 98 103 – 107
4. Thickness (mm) (Single Layer) Finger Palm	Min 0.05 Min 0.05	Min 0.08 Min 0.08
5. Physical Properties Before Aging Tensile Strength (MPa) Ultimate Elongation (%) After Aging Tensile Strength (MPa) Ultimate Elongation (%)	Min 14 Min 500 Min 14 Min 400	15 – 21 550 – 630 14 – 22 520 – 610
6. Powder Content	Max 2.0mg/glove	Below 2 mg/glove

- 8.0 The performance data of the glove as shown above meet the ASTM D6319-00a **E3** Standard and FDA's requirement.
Powder content is below 2 mg per glove which meet the FDA Requirements.
- 9.0 The Bio-compatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buehler) test.
The gloves pass the Bio-compatibility Test.
- 10.0 Conclusion

We conclude that the Multiple Private Labeled Non-Sterile Black Colour Powder Free Nitrile Examination Gloves meets:

- ASTM D6319-00a Standard
- FDA pinhole requirements
- Are below the maximum Powder Residual Content as specified in ASTM D6319-00a **E3**



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2006

YTY Industry (Manjung) Sdn. Bhd.
C/O Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D'Emerald
Sparks, Nevada 89434-9550

Re: K061553
Trade/Device Name: Non-Sterile, Powder-Free, Black Nitrile
Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: June 1, 2006
Received: June 7, 2006

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

APPLICANT: YTY INDUSTRY (MANJUNG) SDN. BHD.

510(k) NUMBER: _____

DEVICE NAME: NON-STERILE, POWDER-FREE, BLACK NITRILE EXAMINATION GLOVE

Indications For Use:

This Non-Sterile, Powder-Free, Black Nitrile Examination Glove is a disposable device intended for medical purposes, that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use..... AND/OR Over-The-Counter Use ...**X**.....
Per 21 CFR 801.109 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley H. Murphy MD 7/14/04
 (Don Sign-Off)
 Division of Anesthesiology, General Hospital,
 Pain Control, Dental Devices
 License: K061533